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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,072	12/04/2003	Ron Heil	GUID.626PA	7645

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EXAMINER

GREENE, DANA D

ART UNIT PAPER NUMBER

3762

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,072

Applicant(s)

HEIL ET AL.

Examiner

Dana D. Greene

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/2/05.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-66 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-9, 27-28, 33-42, 48, and 49 stand rejected under 35 U.S.C. §102(b) as being anticipated by Shapland et al. (US 5,628,730, hereinafter "Shapland"). Shapland is considered to disclose:

a lead body (see col. 9, In. 10-12, Shapland). The disclosed leads are considered to anticipate the claimed lead body because both configurations are able to support a subcutaneous electrode;

an electrode supported by the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient (see col. 8, In. 65 – col. 9, In. 5 and col. 12, In. 5-13, Shapland). The disclosed electrode is considered to anticipate the claimed electrode because both are located within the body of the patient and not within the cavity of the chest;

a driving arrangement coupled to the lead, the driving arrangement configured to provide phoresis delivery of a pharmacological agent from the lead to subcutaneous tissue (see col. 14, In. 23-26, Shapland). The disclosed phoresis means is considered to anticipate the claimed driving arrangement because both employ an electrochemical process in which colloidal particles migrate under the influence of electric potential.

With reference to claim 33, Shapland is considered to disclose:

delivering a lead into subcutaneous non-intrathoracic tissue of a patient, the lead comprising a lead body, an electrode, and a pharmacological agent on the lead and impelling, using phoresis, the pharmacological agent from at least a portion of the lead to the subcutaneous non-intrathoracic tissue (see col. 14, ln. 23-26, Shapland). The disclosed phoresis means is considered to anticipate the claimed driving arrangement because both employ an electrochemical process in which colloidal particles migrate under the influence of electric potential.

Referring to claim 48, Shapland is considered to disclose:

a lead body (see col. 9, ln. 10-12, Shapland). The disclosed leads are considered to anticipate the claimed lead body because both configurations are able to support a subcutaneous electrode;

an electrode coupled to the lead body, the electrode configured for subcutaneous non-intrathoracic placement in a patient (see col. 8, ln. 65 – col. 9, ln. 5 and col. 12, ln. 5-13, Shapland). The disclosed electrode is considered to anticipate the claimed electrode because both are located within the body of the patient and not within the cavity of the chest;

means, coupled to the implantable lead, for impelling a pharmacological agent using phoresis into subcutaneous non-intrathoracic tissue (see col. 14, ln. 23-26, Shapland). The disclosed phoresis means is considered to anticipate the claimed driving arrangement because both employ an electrochemical process in which colloidal particles migrate under the influence of electric potential.

With reference to claim 49, Shapland is considered to disclose a lead wherein the impelling means comprises means for impelling the pharmacological agent using

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electrophoresis (see col. 3, ln. 55-60, Shapland). The disclosed iontophoresis means is considered to anticipate the claimed means for using electrophoresis because both transport a drug across a medium and employ an electrochemical process in which colloidal particles and/or macromolecules with a net electric charge migrate under the influence of an electric potential.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5, 10-17, 25-26, 29-32, 44-47, 50-54, and 63-66 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Shapland in view of Altman et al. (US 6,416,510, hereinafter "Altman"). Shapland is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed array and can configuration. However, Altman is considered to disclose this claimed array and can. With reference to claim 4, Altman is considered to disclose the claimed invention as discussed above including an electrode array (see col. 19, ln. 1-15, Altman). The disclosed device is considered to anticipate the claimed electrode array because both devices are capable of sensing cardiac activity and delivering cardiac stimulation energy. It would have been obvious to one of ordinary skill in the art to combine the teachings of Shapland with the electrode array of Altman for the purpose of

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sensing cardiac activity and delivering cardiac stimulation energy in an ITCS device configuration employing an active can or a configuration employing a non-active can.

With reference to claim 5, Altman is considered to disclose the claimed invention as discussed above including the conductor (see col. 11, ln. 45-50, Altman). The disclosed conductor is considered to anticipate the claimed conductor because both devices must be present for the deliver of pharmacological agents to monitor the electrical action of the heart.

Referring to claims 10-12 and 25-26, Altman is considered to disclose the claimed invention as discussed above including the porous region and the polymeric structure (see col. 6, ln. 56-65, Altman). It would have been obvious to one of ordinary skill in the art to combine the teachings of Shapland with the porous regions of Altman for the application of an electric field across the polymer substrate and the incorporation of the pharmacological agents with the lead.

With reference to claims 13-17, 29-32, 44-47, 50-54, and 63-66 Altman is considered to disclose the claimed invention as discussed above including the therapeutic treatment in the form of an anesthetic, anti-inflammatory, antiseptic, or agent providing vasoconstriction (see col. 2, ln. 1-65, Altman).

With reference to claims 18-24 and 55-58, Altman is considered to disclose the claimed invention as discussed above including:

a can coupled to the lead, the can configured to provide phoresis delivery of a pharmacological agent from at least a portion of the can to subcutaneous tissue (see col. 19, ln. 10-15, Altman). It would have been obvious to one of ordinary skill in the art

to combine the teachings of Shapland with Altman for the purpose of holding pharmacological agents for subsequent distribution.

Claim 3 is rejected under 35 U.S.C. §103(a) as being unpatentable over Shapland in view of Gray (US 6,144,879, hereinafter "Gray"). Shapland is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed transducer. However, Gray is considered to disclose the claimed transducer (see col. 5, ln. 36-50, Gray). It would have been obvious to one of ordinary skill in the art to combine the teachings of Shapland with the transducer taught in Gray for the purpose of converting one form of energy to another.

Claim 43 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Shapland in view of Stokes (US 4,506,680, hereinafter "Stokes"). Shapland is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed sheath. However, Stokes is considered to disclose the claimed sheath (see col. 2, ln. 30-50, Stokes). It would have been obvious to one of ordinary skill in the art to combine the teachings of Shapland with the sheath taught in Stokes for the purpose of providing a sheath and inserting the lead into the sheath to deliver the lead into subcutaneous non-intrathoracic tissue.

Claims 59-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Shapland in view of Altman, and further in view of Schroepfel et al. (US 5,749,909, hereinafter "Schroepfel"). Altman is considered to disclose the claimed invention as discussed above except for the claimed power signal voltages and frequency. However, Schroepfel is considered to teach the claimed voltages and frequency (see col. 2, ln. 35-50 and col. 8, ln. 47-64, Schroepfel). It would have been obvious to one of

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ordinary skill in the art to combine the teachings of Shapland and Altman with the energy transmission system of Schroepfel for the purpose of driving the pharmacological agent using sonophoresis and applying a direct current (DC) signal to create an electric field in the tissue capable of driving the pharmacological agent using electrophoresis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene

